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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,666	07/13/2001	Lorraine J. Giver	0184.310US	6235

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EXAMINER	
NASHED, NASHAAT T	

ART UNIT	PAPER NUMBER
1652	13

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/905,666	Giver et al.
Examiner	**Art Unit**
Nashaat T. Nashed	1652

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 13, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18, 20, 49-59, 73-81, 83, 131, 134, and 181-210* is/are pending in the application.

4a) Of the above, claim(s) *190-210* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18, 50-59, 73-81, 83, 131, 134, and 181-189* is/are rejected.

7) ☒ Claim(s) *20 and 49* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7 & 8*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-180 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-54	Claims 1-85, 131-134 and 179, drawn to one of the polypeptides of SEQ ID NO's: 55-108, respectively, classified in Class 435, subclass 198.
Groups 55-108	Claims 86 and 87, drawn to antibodies specific for one of the polypeptides of SEQ ID NO's: 55-108, respectively, classified in Class 530, subclass 387.1.
Groups 109-162	Claims 88-130, 135-137, and 169-178, drawn to a nucleic acid sequence encoding one of the polypeptides of SEQ ID NO's: 55-108, vector, host and a recombinant method of making said polypeptide, classified in Class 536, subclass 23.2 and Class 435, subclass 198.
Groups 163-216	Claims 138-156, 167, and 168, drawn to a database comprising the nucleotides of SEQ ID NO's: 1-54 and the polypeptides of SEQ ID NO: 55-108, respectively and method of use in manipulating nucleic acid sequences and polypeptide sequences, classified in Class 702, subclass 20.
Groups 217-270	Claims 157-164, drawn to a method of a modified recombinant nucleic acid encoding the polypeptides of SEQ ID NO's: 55-108, respectively, classified in Class 435, subclass 440.
Group 271	Claims 165 and 166, drawn to nucleic acid library, classified in Class 435, subclass 252.3.
Groups 272-325	Claim 180, drawn to method of hydrolyzing a lipid by contacting with any of the polypeptides of SEQ ID NO's: 55-108, classified in Class 435, subclass 18.

The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Groups 1-54 are independent chemical entities and require different searches in the patent and non-patent literature.

The antibodies of Groups 55-108 are independent chemical entities and require different searches in the patent and non-patent literature.

The nucleic acid sequences of Groups 109-162 are independent chemical entities and require different searches in the patent and non-patent literature. Claims drawn to method of making the enzyme using recombinant nucleic acid are placed with the appropriate nucleic acid of Groups 109-162 because, although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search them in addition to the nucleic acid sequence.

The polypeptides of Groups 1-54, the antibodies of Groups 55-108, and the nucleic acid sequences of Groups 109-162, the are independent chemical entities and require different literature searches.

The antibodies of Groups 55-108, and those of the database of Groups 163-216, the methods of manipulating the nucleic acid sequences of Groups 217-270, the method of modifying the nucleic acid of Groups 271-324 and the method of hydrolyzing lipids of Groups 326-379 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the databases of Groups 163-216 do not contain antibodies, and the methods of Group 217-324 and 326-379 do not utilize the antibodies of Groups 55-108.

The polypeptide molecules of Groups 1-54, the nucleic acid molecules of Groups 109-162, and the database of Groups 163-216 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid sequences and polypeptide sequences in the data bases are structure representation of the nucleic acid and polypeptide molecules, and therefore, they could not be used with the molecules they represent.

The database of Groups 163-216 and the methods of modifying nucleic acid and polypeptides of groups 217-270 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of modification of the nucleic acid sequences and the polypeptides may be carried out without the use of the databases by well known methods in the art such as random mutagenesis and chemical mutagenesis.

The polypeptides of Groups 1-54 and the antibodies of Groups 55-108, and those methods of Groups 217-270 and the nucleic acid library of Group 270 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the methods of Groups of Groups 217-270 do not utilize the polypeptides of Groups 1-54 or the antibodies of Groups 217-270, and the library of Group 270 does not contain polypeptide or antibodies.

The polypeptides of Groups 1-54 and the methods of Groups 272-325, respectively, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups 1-54 can be utilized in other methods such as in a method to make antibodies, whereas the methods can be practiced with other known lipases or chemical means.

The antibodies of Groups 55-108 and the methods of Groups 272-325 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the methods of Groups 272-325 do not utilize any of antibodies of Groups 55-108.

The nucleic acid molecules of Groups 109-162 and the methods of Groups 217-270, respectively, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid molecules of Groups 109-162 can be utilized in other methods such as in a recombinant method of making the polypeptide.

Inventions of Groups 109-162, and 271-325 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid sequences of Groups 109-162 are not member of the library of Group 271, and are not utilized in the methods of lipid hydrolysis of Groups 272-325.

Inventions of Groups 163-216, and those of Groups 271-325 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the database of Groups 163-216 are not usable with the library and not used by the methods of lipid hydrolysis of Groups 272-325.

Inventions of Groups 217-270 and 271 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the library of Group 271 can be made by other methods.

Inventions of Groups 217-270 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the two sets of invention are independent methods having different steps and products.

Inventions of Groups 217-270, and those of Groups 272-325 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the two sets of invention are independent methods having different steps and products.

Inventions of Groups 272-325 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the two sets of invention are independent methods having different steps and products.

Inventions of Group 271 and those of Groups 272-325 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the library of Group 271 is not utilized by any of the method of Groups 272-325.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Sharon Fujita on May 13 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-85, 131-134 and 179 with regard to the polypeptide of SEQ ID NO: 55 and encoded by the nucleic acid sequence of SEQ ID NO: 1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 86-130, 135-178 and 180 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

In addition to the election by telephone, Applicants have filed a written response to the telephonic restriction requirement and an amendment on May 13, 2003. Accordingly, claims 1-17, 19, 21-48, 60-71, 82, 84-130, 132, 133, 135-180, have been canceled, new claims 181-210 have been entered and claims 18, 20, 49, 50, 72-80, 83, 131, 134 have been entered.

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is no search burden on the examiner to search the polypeptide (SEQ ID NO: 55) of Group 1 and the nucleic acid of SEQ ID NO: 1 of Group 109. This is not found persuasive because, although the two groups may have an overlapping fields of search, the two invention are independent chemical entity and require separate searches in the patent and non-patent literature.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 190-210 are also withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim 18, 20, 49-59, 73-81, 83, 131, 134, 181-189 are under consideration.

New formal drawings are required in this application because the drawing filed on July 13, 2001 contains many nucleic and amino acid sequences which are not identified specifically by a sequence identification number in addition to many informalities. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The use of the trademark names have been noted in this application, see for example pages 106, lines 19-21 and page 112, line 14. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see for example page 1, line 22. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 72-81, 83, 131, 134, and 181-187 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 18, 72-81, 83, 131, 134, and 181-187 are directed to all possible polypeptide having 94% (claim 18), 95% (claim 182), 96% (claim 183), 97% (claim 184), or 98% (claim 185) sequence identity to the mature region of SEQ ID NO: 55. The specification, however, only provides six representative species from *Bacillus* species encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polypeptides by any identifying structural characteristics or properties other than the lipase activity cited in claim 50, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 18, 50-59, 72-81, 83, 131, 134, and 181-189 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the polypeptide of SEQ ID NO: 55 or the mature form thereof. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to all possible variants of SEQ ID NO: 55 which have 94-98% sequence

homology to SEQ ID NO: 55. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses all natural and man made variants of SEQ ID NO: 55 which have sequence identity of 94-98% to SEQ ID NO: 55 having any function. The specification provides guidance and examples in the form of an assay to identify a lipase producing *Bacillus* species (example 1) and a method of screening lipase homologs for enantioselectivity (example 2). Also, the specification teaches that the polypeptide of SEQ ID NO: 55 does not display enantioselectivity with neryl-butyrate and geranyl-butyrate, see page 26, second paragraph. While molecular biological techniques and genetic manipulation to make and use the constructs claimed are known in the prior art and the skill of the artisan are well developed, knowledge regarding other biological source for the polypeptide, method of their isolation and purification, the nucleic acid encoding said polypeptide, the utility of the polypeptide, the structure of a polypeptide having enantioselective lipase activity, and the insertion, deletion, substitution and combination thereof mutant that have any function is lacking. Thus, searching for a polypeptide having a 94-98% sequence homology to SEQ ID NO: 55 with specific function and chemical properties such as those in claims 50-59 is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a naturally occurring or man-made polypeptide having 94-98% sequence homology to SEQ ID NO: 55 and having a particular chemical or biological function such as being enantioselective toward neryl-butyrate is enormous. Since routine experimentation in the art does not include screening vast numbers of organisms in their ability to produce a polypeptide having 94-98% sequence homology to SEQ ID NO: 55; or screen DNA, cDNA or man-made libraries for a nucleic acid sequence encoding a polypeptide which is 94-98% homologous to SEQ ID NO: 55, and determining its use where the expectation of obtaining the desired polypeptide is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the biological source of the polypeptide, the utility of a variant polypeptide and its chemical properties, the amino acid which can be deleted, inserted or substituted without adverse effect on a desired function. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 53-55, 57, 59, 73, 77, 78, 81, and 189 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

(a) Claims 53 and 78 contains the undefined abbreviations DMF, FLAG and GST. Abbreviations and acronyms must be defined at least once in the claims. For examination purposes only, it is assumed that DMF and GST are the abbreviation of the organic solvent N,N-dimethylformamide and glutathione S-transferase. It is also assumed that the lipase activity of claim 53 is observed in neat DMF, i. e., 100% pure DMF. The examiner could make an assumption with regard to the abbreviation FLAG.

(b) The chemical names "neryl-butyrate" in claim 55, and "oxacyclotridecan" in claims 59 render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The chemical names are not proper chemical names and they could not be found in prior art search which included the registry database of chemical abstract and Merck index. Also, the specification have not identified the chemicals by a proper chemical names or structures.

(c) The phrases "methyl esters" in claim 57, "precursor polypeptide" in claim 73, "purification subsequence" in claims 77 and 78, and "GST fusion" in claim 78 render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The word "subsequence" is repugnant to one of ordinary skill in the art because if it means "a part of a sequence"!, it should be called "a sequence or domain". For examination purposes only, the phrases "methyl esters", "precursor polypeptide", "purification sequence" and "GST fusion" are assumed to mean ----methyl esters of fatty acids----, "a proenzyme sequence", ----affinity sequence-----, and ----glutathione S-transferase fusion-----, respectively.

(d) The phrase "heat treatment" in claim 54 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The specification does not describe or exemplify the heat treatment and one of ordinary skill in the art would not know the exact meaning of the phrase. For examination purposes only, the phrase is taken to mean any heat treatment including freezing, thawing, and boiling in aqueous solvent or organic solvent for any length of time.

(e) The phrase "an organic derivatizing agent" in claim 81 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

(f) The phrase "under stringent conditions" in claim 189 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The prior art contains several sets of hybridization conditions each of which known as stringent conditions.

Since the result of a hybridization experiment varies with the "stringent conditions used", the claim is considered indefinite. It is noted that the specification exemplifies a set of stringent hybridization and wash conditions on page 49, first paragraph. The incorporation of said conditions will obviate this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 189 is rejected under 35 U.S.C. § 102(b) as being anticipated by Dartois *et al.* (IDS paper number 7, reference number C1: Biochim. et Biophys. Acta **1992**,1131, 253-260).

Dartois *et al.* teach the nucleic acid sequence encoding a lipase from *Bacillus subtilis* 168, see the abstract and Figure 2. The nucleic acid sequence in Figure 2 has 93.4% sequence identity to the nucleic acid sequence of SEQ ID NO: 1 of the instant application and would be expected to hybridize to SEQ ID NO: 1 of the instant application under any stringent hybridization condition. Also, the polypeptide of SEQ ID NO: 55 has 93.4% sequence identity to the polypeptide taught by Dartois *et al.* which contains more than 45 contagious amino acid residues identical to those in SEQ ID NO: 55, compare residues 65-114 of SEQ ID NO: 55 to the corresponding amino acid residues in the sequence taught in Figure 2. It should be noted that the amino acid sequence taught by Dartois *et al.* comprises at least residues L.S.-2, The-13 and Sea-18 identical to those of SEQ ID NO: 55 and correspond to L.S.-1, The-14, and Sea 17 of SEQ ID NO: 75.

Claims 20 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner